REMARKS

The non-final Office Action dated May 1, 2009 has been carefully reviewed and the foregoing amendments and following remarks are made in response thereto.

Claims 22-39 were pending in the application at the time the Office Action dated May 1, 2009 was issued. Claims 22-24, 32 and 38 have been amended. New claim 40 has been added. Claim 22 has been amended to specify that the isolated polynucleotide comprises the sequence of nucleotides 1525-1643 of SEQ ID NO: 113. Claim 23 has been amended to clarify that the isolated polynucleotide comprises the sequence from the recited group of sequences. Claim 24 has been amended to specify that the isolated polynucleotide comprises the sequence of nucleotides 1525-1643 of SEQ ID NO: 113. Claim 32 has been rewritten in independent form. Claim 38 has been amended to specify that the isolated polynucleotide comprises a 20-mer to a 600-mer complementary to the sequence of SEQ ID NO: 12, SEQ ID NO: 60, or nucleotides 1-1643 of SEQ ID NO: 113. Support for this amendment can be found in the specification at page 12, line 24 to page 13, line 5. New claim 40 is directed to a genetic construct comprising a sequence of claim 38. Support for new claim 40 can be found in the specification at least at page 4, lines 12-18 and page 15, lines 6-9. No new matter has been added by way of these amendments. Upon entry of this amendment, claims 22-40 will be pending in the application.

I. Objection to the Specification

The Examiner has objected to the specification as she believes that the previously filed amendment to incorporate essential material into the specification was improper. Specifically, the Examiner states that the statement required by 37 CFR §1.57(f) was missing. Applicants submitted the following statement in the "Remarks" section on page 9 of the Amendment/Response filed December 5, 2008: "The material that has been added is the material that was incorporated by reference in the present application and no new matter has been added by way of these amendments." During a telephone conference with Applicants' representative in early July, the Examiner acknowledged that she had overlooked this statement and that the statement was sufficient to comply with 37 CFR §1.57(f). Because the required statement was previously submitted, Applicants respectfully submit that the incorporation of essential material

made in the previously filed Amendment/Response was proper and the objection to the specification should be withdrawn.

II. Rejections under 35 U.S.C. §112, 1st paragraph

Lack of written description

Claims 22-37 have been rejected under 35 U.S.C. §112, 1st paragraph for allegedly lacking written description. The Office Action states that the specification does not disclose whether the claimed fragments of SEQ ID NO: 113 have the claimed vascular tissue-specific regulatory function. It appears that the Examiner has reiterated this rejection because she believed that the prior amendment to incorporate essential material was improper. As discussed above in response to the objection to the specification, Applicants have complied with the requirements to incorporate essential material by the inclusion of the statement in the "Remarks" section of the last response. As such, the specification as amended in the Amendment/Response dated December 5, 2008 discloses specific fragments of SEQ ID NO: 113 that exhibit the vascular tissue-specific promoter activity and thus sufficiently describes the claimed invention. Therefore, Applicants request that the rejection of claims 22-37 under 35 U.S.C. §112, 1st paragraph be withdrawn.

Claim 22 is further rejected under 35 U.S.C. §112, 1st paragraph for allegedly lacking written description. The Examiner asserts that the phrase "an isolated polynucleotide comprising a sequence of nucleotides 1525-1643 of SEQ ID NO: 113" encompasses fragments of the sequence of nucleotides 1525-1643 and that the specification does not describe fragments of this sequence that have the functional promoter activity. To expedite allowance of the claims, Applicants have adopted the Examiner's suggestion to amend claim 22 to recite "an isolated polynucleotide comprising the sequence of nucleotides 1525-1643 of SEQ ID NO: 113." Therefore, the further rejection of claim 22 under 35 U.S.C. §112, 1st paragraph should be withdrawn.

Claim 32 is further rejected under 35 U.S.C. §112, 1st paragraph for allegedly lacking written description. Claim 32 is drawn to a genetic construct comprising one of the vascular tissue-specific promoter sequences recited in claims 22-24 under the control of a heterologous

promoter sequence. The vascular tissue-specific promoter sequences of claims 22-24 can be inserted into the claimed construct as a direct or inverted repeat. The Examiner states that the specification does not disclose whether direct or inverted repeats of the claimed promoter sequences have promoter function and that it is known in the art that an inverted repeat of a promoter sequence does not retain the same promoter activity. Thus, the Examiner asserts that the specification fails to describe the claimed genus of nucleotides and therefore, claim 32 does not comply with the written description requirement. Applicants respectfully traverse the rejection.

Although Applicants believe that claim 32 as written did not require the polynucleotide sequences of claims 22-24 to have functional promoter activity in the claimed genetic construct, Applicants have rewritten claim 32 as an independent claim directed to a genetic construct comprising a polynucleotide containing the sequence of nucleotides 1525-1643 of SEQ ID NO: 113 under the control of a heterologous promoter, wherein the polynucleotide can be inserted as a direct or inverted repeat. Currently amended claim 32 does not require the polynucleotide comprising the sequence of nucleotides 1525-1643 of SEQ ID NO: 113 to have functional promoter activity. One of skill in the art would understand that the polynucleotide comprising the sequence of nucleotides 1525-1643 of SEQ ID NO: 113 would not need to be functional in the claimed construct as such a construct is useful for transcriptional gene silencing. As disclosed in the specification at page 15, lines 6-9, the present invention includes the use of a "genetic construct to produce gene knockouts by transcriptional gene silencing, for example, a construct comprising an inverted repeat of a promoter sequence or a promoter fragment of the present invention under the control of a different promoter." Thus, one of skill in the art would appreciate that the promoter sequence used to induce transcriptional silencing would not have to be functional. The specification describes the structure of the claimed sequences and how to insert the promoter sequence into the genetic construct to achieve transcriptional silencing. Applicants submit that this information is sufficient to comply with the written description requirement. Therefore, the rejection of claim 32 under 35 U.S.C. §112, 1st paragraph should be withdrawn.

Lack of enablement

Claim 38 is rejected under 35 U.S.C. §112, 1st paragraph for allegedly lacking enablement. The Examiner states that the specification does not disclose fragments of SEQ ID NO: 12, SEQ ID NO: 60 or nucleotides 1-1643 of SEQ ID NO: 113 as short as 20-mers which possess promoter activity. The Examiner further argues that one of skill in the art would not know how to use fragments of a promoter except as part of a functional promoter sequence and the skilled artisan would have to engage in undue experimentation to use such fragments. Applicants respectfully disagree with the Examiner and traverse the rejection.

Applicants note that claim 38 does not require the isolated polynucleotide to have functional promoter activity. Further, claim 38 has been amended to specify that the polynucleotide comprises 20-mers to 600-mers that are complementary to SEQ ID NO: 12, SEQ ID NO: 60, or nucleotides 1-1643 of SEQ ID NO: 113. Contrary to the Examiner's assertion that a skilled artisan would not know how to use such fragments of a promoter sequence, one of skill in the art would immediately recognize that small fragments of the promoter sequences, such as 20-mers to 100-mers, could be used as oligonucleotide probes and primers. In fact, the specification describes that oligonucleotide probes and primers can be designed from the inventive promoter sequences. For instance, at page 20, lines 1-13, the specification discloses that oligonucleotide probes and primers corresponding to the promoter sequences of the present invention may be from about 8 to 100 base pairs in length. The specification discloses the structure of SEQ ID NOs: 12, 60, and 113 as well as how to design probes and primers from the sequences. Moreover, it is within the skill of the ordinary artisan to prepare appropriate probe and primer sequences from a given nucleotide sequence. In addition, the skilled artisan would understand that such complementary fragments of the promoter sequences can be used in genetic constructs for promoter silencing. Thus, Applicants submit that the skilled artisan provided with the disclosure of the instant specification could make and use the claimed fragments of the promoter sequences. Applicants respectfully request that the rejection of claim 38 under 35 U.S.C. §112, 1st paragraph be withdrawn.

III. Rejections under 35 U.S.C. §112, 2nd paragraph

Claims 23, and 25-37 are rejected under 35 U.S.C. §112, 2nd paragraph for allegedly being indefinite and failing to particularly point out and distinctly claim the invention. The Examiner believes that the phrase "the isolated polynucleotide of claim 22, wherein the nucleotide comprises a sequence from the group consisting of" renders the claim indefinite because it is unclear whether the claimed polynucleotide comprises a sequence from the Markush group in addition to the sequence of nucleotides 1525-1643 of SEQ ID NO: 113 or whether the claimed polynucleotide is one of the sequences in the group. Claims 25-37 were rejected for the same reason because they depend from claim 23. Although Applicants do not agree with the Examiner's interpretation of the claim, claim 23 has been amended to clarify that the claimed polynucleotide comprises one of the sequences from the recited group. The rejection of the claims under 35 U.S.C. §112, 2nd paragraph should be withdrawn.

IV. Rejections under 35 U.S.C. §102

Claim 39 is rejected under 35 U.S.C. §102(b) as being anticipated by AAC62810, which published February 2, 2001. The Examiner states that SEQ ID NO: 113 was not disclosed until U.S. Application No. 10/137,036, filed April 30, 2002, and thus claim 39 has a priority date of April 30, 2002. The Examiner asserts that the sequence of AAC62810 comprises 1662 bp from SEQ ID NO: 113, and therefore anticipates the claim. Applicants traverse the rejection.

SEQ ID NO: 113 was first disclosed in U.S. Application No. 09/598,401, filed June 20, 2000 to which the instant application claims priority. Thus, the priority date for claim 39 is June 20, 2000, which is before the publication date of AAC62810. Therefore, AAC62810 is not available as prior art and the rejection of claim 39 under 35 U.S.C. §102(b) is improper and should be withdrawn. It is requested that the Examiner reconsider this rejection in view of Applicants' priority claim, and withdrawn this rejection.

V. Obviousness-type Double Patenting

Claims 22-39 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,365,186 ("the '186 patent).

Applicants submit that this double patenting rejections is improper. Applicants assert that the present claims dominate the claims of the '186 patent. As noted in the MPEP Section 804 (page 800-19) domination and double patenting are two separate issues. Applicants submit that the present patent application contains broader claims which encompass the invention claimed in a narrower or more specific manner in the '186 patent.

Applicants remind the Examiner that double patenting rejections are made as a matter of public policy to prevent the unjust extension of patent rights. However, in the present set of facts, Applicants submit that the '186 patent has an expiration date of November 7, 2023 plus 224 days of patent term adjustment. Whereas the present patent will expire on March 25, 2019 plus any awarded patent term adjustment, and therefore, granting the present application without a terminal disclaimer does not unjustly extend the rights because the present application will expire before the expiration date of the '186 patent. In view of these arguments, it is requested that this rejection based on obviousness-type double patenting be withdrawn.

VI. Claim Objections

Claim 24 is objected to as allegedly being an improper dependent claim for failing to further limit the subject matter of a previous claim. The Examiner interprets claim 24 to encompass an isolated polynucleotide comprising any sequence of SEQ ID NO: 113 whereas claim 22 from which claim 24 depends is drawn to an isolated polynucleotide comprising nucleotides 1525-1643 of SEQ ID NO: 113. Thus, the Examiner asserts that claim 24 is broader than claim 22. Without agreeing with the Examiner's interpretation of claim 24, claim 24 has been amended to clarify that the isolated polynucleotide comprises the sequence of SEQ ID NO: 113. Thus, claim 24 is narrower than claim 22 and is a proper dependent claim. Withdrawal of the objection to claim 24 is respectfully requested.

CONCLUSION

This reply is fully responsive to the Office Action dated May 1, 2009. In view of the above amendments and remarks, it is believed that the present set of claims are now in condition for allowance. If, in the opinion of the Examiner, a further telephonic conference would expedite any minor issues with regard to the pending claims, the Examiner is invited to call the undersigned practitioner.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-1283.

Respectfully submitted,
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